BTL Industries

DECLARATION OF CONFORMITY

for CE – marking according to Annex II of Medical Devices Directive 93/42/EEC

Manufacturer:	**BTL Industries Limited** **Suite 401 Albany House** **324-326 Regents Street** **London** **W1B 3BL** **United Kingdom**

The **BTL Industries Ltd.** herewith declares under its sole responsibility that the product

Product Name:	**Combined therapy devices**
Type:	**BTL-5000 Series v1.xx** **BTL-4000 Series v1.xx**
Product Name:	**Electrotherapy devices**
Type:	**BTL-06 v3.xx** **BTL-5000 Puls v1.xx** **BTL-4000 Puls v1.xx**
Product Name:	**Ultraound therapy devices**
Type:	**BTL-12 v2.xx** **BTL vac v1.xx**
Product Name:	**Ultraound therapy devices**
Type:	**BTL-07p v4.xx** **BTL-5000 Sono v1.xx** **BTL-4000 Sono v1.xx**
Product Name:	**Laser therapy devices**
Type:	**BTL-10 v5.xx** **BTL-2000 v5.xx** **BTL-5000 Laser v1.xx** **BTL-4000 Laser v1.xx**
Product Name:	**Magnetotherapy devices**
Type:	**BTL-09 v4.xx**
Risk Classification:	**Class IIb**

conforms with the applicable regulation:

Directive:	**MDD 93/42/EEC**
Quality Assurance Standards:	**ISO 13485 : 2003**
Procedural Standards:	**EN 60601-1 + A2** **EN 60601-1-1** **EN 60601-1-2** **EN 60601-2-10** **EN 60601-2-5** **EN 60601-2-22** **EN 60825-1** **EN ISO 14971** **ISO 10993-1**

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Signature: Daniela Marx

Daniela Marx
Director of BTL Industries Limited